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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Proposed Regulations for Establishment and Maintenance of Food Records
FDA Docket No. 02N-0277
68 Fed. Reg. 25188 (May 9, 2003)

These comments are submitted by the American Forest & Paper Association (AF&PA), the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents member companies engaged in growing, harvesting, and processing wood and wood fiber, manufacturing pulp, paper, and paperboard products from both virgin and recycled fiber, and producing engineered and traditional wood products. AF&PA members include manufacturers of over eighty percent of the paper, wood, and forest products produced in the United States. Because virtually all of the packaging and food contact facilities of the member companies—as well as all of their suppliers—would be required to establish and maintain records under the proposed regulations, AF&PA is submitting these comments to ensure that the Food and Drug Administration (FDA) considers the full impact of its proposal on the industry.

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The regulations as drafted will impose a very large burden on AF&PA member companies, with only a very limited and theoretical increase, if any, in the safety of the food supply. While AF&PA and its members agree with FDA's decision not to apply the proposed regulations to outer packaging, the same logic that supports that exclusion applies equally to food contact materials. In proposing that the recordkeeping requirements apply to food contact articles, FDA has created an unreasonable and unjustified burden on the industry and its suppliers. Under FDA's proposed approach, there is no limit to the suppliers of components and precursor substances who would be required to establish and maintain records. Removing food contact facilities from the ambit of the recordkeeping regulations is consistent with the clear intent of the authorizing legislation and FDA's mandate to ensure the safety of the United States food supply in the least burdensome means possible.

I. FDA's Proposed Extension of the Recordkeeping Requirements to Food Contact Facilities Is Unjustified Given the Scope and Purpose of the Bioterrorism Act

A. Subjecting Food Contact Facilities to the Recordkeeping Requirements Will Not Further the Purpose of the Bioterrorism Act

The Conference Report on the Bioterrorism Act states that the intent of the bill is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 107 (May 21, 2002). Thus, all the requirements imposed by the Act must be directed at achieving this goal. While the proposed recordkeeping rules might further this purpose when applied to conventional food, they will not do so when applied to food contact materials.

More specifically, Section 306(b) of the Bioterrorism Act, which the proposed rules purport to implement, authorizes FDA to establish recordkeeping requirements only where such records are needed to identify the immediate previous source and immediate subsequent recipient of food "in order to address credible threats of serious adverse health consequences or death to humans or animals." FDA asserts in the preamble to the proposed rules that the regulations "would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food." 68 Fed. Reg. 25188 (May 9, 2003). However, FDA has put forward no evidence that food contact materials could present any such threat or that the application of the proposed regulations to these materials would help the agency respond to or contain such a threat.

It is unrealistic to believe that a terrorist attack on the food supply will be carried out through food contact substances. As a technical matter, it would be virtually impossible to insert a poison in contact materials with a sustained release mechanism to contaminate food, without the full cooperation of the materials manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. Food contact manufacturers and food processors have routine procedures in place to ensure that their contact materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage. Accordingly, there is no reason to believe that applying the recordkeeping requirements to food contact substances would further the purpose of the Bioterrorism Act or FDA's stated goal of the proposed regulations.

AF&PA fully agrees with FDA's determination not to extend the recordkeeping requirements to outer food packaging, as there appears to be no actual risk that harm could be perpetrated through outer packaging. However, FDA fails to provide any basis for distinguishing the level of risk posed by food contact substances and outer food packaging, other than its statement that "the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food." 68 Fed. Reg. at 25190. This bare assertion is simply insufficient to justify burdening the food contact industry with the substantial obligations imposed by the proposed recordkeeping regulations. Moreover, without an explanation, this unsupported distinction between the dangers posed by outer packaging and food contact materials appears to be arbitrary and capricious, in violation of the Administrative Procedure Act.

The exclusion of outer food packaging accomplishes nothing unless all food packaging is excluded. Virtually all packaging companies handle both outer packaging and food contact substances. FDA's assumption that half of the manufacturers and distributors of packaging handle outer packaging materials exclusive of food contact substances (68 Fed. Reg. at 25212) is flatly incorrect. As a practical matter, packaging companies will find it more expedient to keep records on all materials -- both outer packaging and contact substances -- rather than to document only the food contact materials, because many of the same materials can be used for both purposes and it would be prohibitively expensive to segregate these uses. This would result in a recordkeeping requirement for virtually all facilities that manufacture packaging and packaging components operated by AF&PA members, and all of their suppliers, under FDA's proposed approach. The actual burden of the proposal is plainly unjustified in light of the

purpose and scope of the Bioterrorism Act, particularly where FDA has acknowledged the minimal risk to health posed by outer food packaging.

The examples of foodborne outbreaks that could be averted by the proposed requirements, to which FDA refers in the preamble, demonstrate that the appropriate realm for these regulations is conventional food. Beginning on page 25225 of the preamble, FDA sets out the cost of these outbreaks. The "vehicles" for these five outbreaks are all conventional foods, and have nothing to do with packaging or food contact articles. If FDA seriously thinks that food contact materials pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack and would have shown that these provisions will minimize that risk, in an attempt to justify the immense burden being placed on the industry. FDA has provided no such cost minimization justification. While FDA must accurately implement the Bioterrorism Act, this proposed regulation goes too far, and imposes a burden without a proper estimate of the benefit or any cost minimization achieved by the proposal. In the absence of such an estimate, FDA's inclusion of food contact materials is completely unjustified.

B. FDA Vastly Underestimates the Burden of the Proposed Regulations

FDA estimates that 73,813 packaging facilities will be subject to the recordkeeping requirements. 68 Fed. Reg. at 25201. This figure represents over 10 percent of all domestic facilities affected by the proposed rule -- a percentage plainly out of proportion to the relative risk posed by food contact materials. FDA's estimate, however, ignores several aspects that result in an underestimate of the burden imposed.

First, FDA adopts an expansive approach to the definition of "food." It would include all "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. at 25238. The potential list of food contact articles is tremendous. For example, the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, are "food" under the statute. Articles typically referred to as "housewares" -- which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments -- have traditionally been considered outside the scope of FDA's food additive authority, but are still "food" under the FD&C Act. Under FDA's proposed regulations, all facilities manufacturing, processing, packing, or holding these articles must establish and maintain records. Thus, all firms engaged in any of the following industries would be subject to the recordkeeping requirements: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, and utensils. Applying the recordkeeping requirements to this broad variety of products will overwhelm both industry and FDA resources, with no benefit of increased security for the United States food supply.

Second, FDA's estimate of the burden of its proposal fails to account for the wide range of "upstream" manufacturers that make ingredients and components that go into food contact articles. The agency's willingness to extend the definition of food to everything that may possibly be considered food would expand the burden of the recordkeeping requirements exponentially. Any facility engaged in the manufacture, processing, packing, or holding of any component or precursor substance of food contact material would be subjected to the recordkeeping requirements, as any ingredient of an ingredient of something that may migrate into food is considered a "food" under FDA's interpretation. There is no logical end to this chain. For example, all of the distributors and suppliers of raw materials for the entire chemical industry would be included. This paperwork and logistical burden will be immense, with no commensurate increase in the safety of the United States food supply.

Third, most of AF&PA's members and their suppliers produce both food and non-food use products. Because a facility may not know at the time it ships a substance or material whether it is destined for food use, the facility will establish records in an abundance of caution to ensure compliance with regulatory requirements in the event that the substance is in fact used for food at some point down the chain of commerce. This cautious approach will result in a tremendous waste of resources, perhaps leading to the establishment of records for every shipment of every chemical substance that might possibly have a food use.

Fourth, the immense burden posed by the proposed regulations will not fall only on large paper, packaging, and chemical suppliers. Many of the facilities are small independent establishments.

The recycling industry will also be affected, because many food contact articles make use of recycled input. This would include all curbside recycling programs, which are clearly sources of raw materials for food packaging. The paperwork burden imposed by the proposed recordkeeping requirements would overwhelm many of these small facilities. Applying these rules to the recycling industry is simply bad public policy, for it would lead many establishments to leave the business of turning recycled materials into food contact materials because they would not be able to keep up with the recordkeeping requirements.

Finally, FDA's requirements for transporters fail to consider transporters of food contact substances. These transporters are unlikely to be aware that the materials they are transporting -- for example, chemical precursors to these substances or aluminum sheeting -- are considered "food" by FDA. They will have no way of knowing that they are obligated to establish and maintain records regarding the shipment of these materials. If FDA assumes that the facility from which the materials are being sent should advise the shipper of the recordkeeping requirement, then the agency would be imposing an additional notification requirement on the food contact industry that goes beyond what is required by the conventional food industry. There is no justification for this disparate treatment, particularly given the fact that any security risk to the food supply is likely to be posed by conventional food.

Given the extraordinarily high cost of this proposal, FDA should focus on the area in which there is the opportunity to benefit the safety of the United States food supply -- conventional food itself. There is no benefit to applying the recordkeeping requirements to food contact materials, and doing so amounts to nothing more than a waste of resources. FDA has been tasked with an

immense obligation, ensuring the safety of the United States food supply, and it must focus its attention on areas where the expenditure of effort will yield returns in increased safety. Requiring recordkeeping for food contact substances will not achieve this purpose.

II. Inclusion of Food Contact Materials is Not Consistent with FDA's Food Security Preventive Measures Guidance

In January 2002, FDA issued Draft Guidance for food establishments to implement security measures intended to protect the nation's food supply. CFSAN, Draft Guidance: Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance (January 9, 2002). In that guidance, FDA recognized the insignificance of food packaging and other food contact articles in protecting against intentional attacks on the food supply. This Draft Guidance for industry on measures to increase the security of the food supply was directed at conventional food facilities. No mention was made of packaging or food contact facilities. In fact, packaging was mentioned merely as one of the items for which the conventional food facility should establish procedures.

FDA announced the issuance of its Final Guidance with a notice in the Federal Register. 68 Fed. Reg. 13931 (March 21, 2003). In the Final Guidance, FDA goes even further in separating "packaging" from conventional "food," mentioning packaging only in the operations section. The Final Guidance suggests that a conventional food establishment develop procedures to ensure that "only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators and sources for all incoming materials" be used for food packaging and that food establishments inspect incoming materials, including packaging. Final

Guidance, p. 8. Clearly, FDA has itself demonstrated that packaging and food are two separate things.

The Final Guidance recommends that the food establishment evaluate the incoming packaging for the possibility of any threat to public health. Thus, if the food establishment follows the FDA Final Guidance, any possible threat to the food supply from the packaging or other food contact material will already be identified by the food establishment, well before the material ever contacts food. This Final Guidance demonstrates that there is no need to apply the recordkeeping requirements to facilities that manufacture food contact materials as FDA proposes in these regulations.

AF&PA submitted comments to FDA on March 6, 2002 endorsing the initial Guidance and its correct distinction between food establishments and food packaging and other food contact material suppliers, their components, and ingredients. At no time in the comments on the Guidance did the food industry suggest a change in this distinction. If this separation were not considered appropriate by our customers or FDA, the comments of AF&PA would have provoked a rebuttal or clarification that was not made by either.

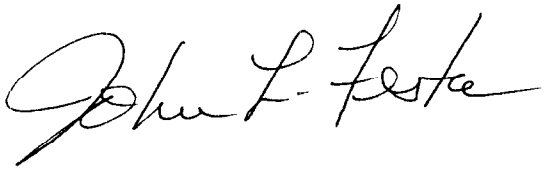
III. Recommendations

For the reasons described in detail above, FDA should not impose recordkeeping requirements on food packaging and food contact facilities at all. The recordkeeping obligation with respect to food contact substances should begin with the first conventional food establishment to receive

the materials -- they will document receipt of these materials as part of their obligation to establish and maintain records regarding the immediate previous source of food components. Such records will provide all the information FDA would need in the highly unlikely event that a foodborne health emergency would be traced to food contact materials, because any possible tampering with contact materials would only become relevant when those materials are applied to conventional food.

Accordingly, FDA should revise its recordkeeping proposal to exclude food contact materials and focus only on conventional foods. This approach is consistent with the statute, the legislative history, and the congressional intent, as well as FDA's mission to protect the safety of the United States food supply under the Bioterrorism Act.

Respectfully submitted,



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